FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

Minutes
May 22, 2007
Dendreon STN 125197/0
Dr.Goodman, Witten: FDA
Gold, Urdal: Dendreon

A meeting was held at Dendreon's request to discuss the application.

Dr.Goodman summarized the review process as based on science, engaging our colleagues in OODP. He noted that the assessment that the uncertainty about efficacy was too great at present to support approval was made by the review team and that Office and Center leadership supported that decision. He also noted that all at FDA are very interested, because of our hope that the product may well be beneficial, in obtaining the needed data as soon as possible that could potentially resolve the question, and that we will all actively engage with Dendreon in considering potential approaches.

Next steps for the application should be discussed with the review team; some preliminary feedback was provided regarding the fact that reanalysis of the TTP from the 9901 study was unlikely to be the path forward. The sponsor was encouraged to submit a proposal for statistical analysis of the ongoing study taking into account the delayed effect seen in the first study for consideration. We expressed our openness to considering creative approaches to data from the ongoing study provided they are scientifically sound.

The sponsor noted that the early adopters were likely to be urologists and community oncologists.

The sponsor inquired as to the limited communication held after the AC meeting. FDA clarified that all questions that needed to be answered for the review to be completed were answered, but that early signaling of the decision was not appropriate.